



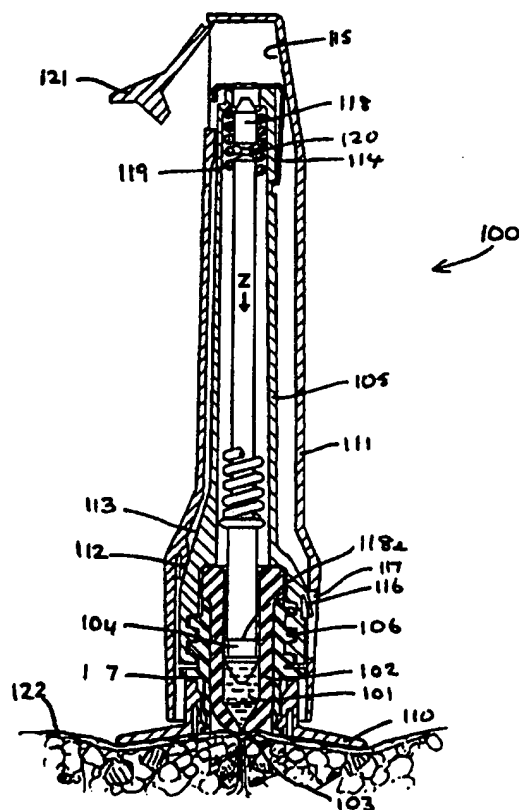
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(54) Title: NEEDLE-LESS INJECTOR

(57) Abstract

An actuator is provided which is adapted, in conjunction with a cartridge, to form a needle-less injector, the cartridge being filled with a liquid to be injected in a subject, and having a liquid outlet and a free piston in contact with the liquid. The actuator comprises an impact member urged by a spring and temporarily restrained by a latch, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet, the spring providing a built-in energy store. A pressure pad surrounds the said liquid outlet and, in use, bears on the subject's skin. The actuator may be formed of two main housing components urged apart by an integral cantilever spring formed on one of them, a safety catch can be provided to prevent inadvertent actuation.



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NEEDLE-LESS INJECTOR

The present invention relates to a needle-less injector, wherein a dose of liquid medicament is discharged in a thin jet at sufficient velocity to penetrate the epidermis of the human, plant or animal to be treated, thus to introduce the medicament into the tissues of the subject.

Needle-less injectors are used as an alternative to hypodermic needle type injectors for delivery of drugs, vaccines, local anaesthetics and other fluids into the tissues. The medicament is discharged in a jet at high velocity to first puncture the epidermis, and thereafter be deposited in the tissues of the subject. A variation is to press the discharge nozzle onto the epidermis and force the medicament at very high pressure through the epidermis.

Such injectors offer many potential benefits: because the hole made by the jet is smaller than that made by a needle, less pain is experienced by the patient when compared with hypodermic needle injection; the availability of the medicament to the capillaries is often enhanced because the spread of the medicament within the tissues is much greater than achieved with a needle injection, which deposits the medicament as a bolus at the needle tip; there is less chance of cross-contamination; animals, which are frequently uncooperative, are more easily injected, because there is no risk of a needle breaking or bending, and the injection is accomplished much faster than needle injection; there is no needle disposal problem; the risk of so-called needle-stick injury is eliminated.

Prior art devices typically use a spring-loaded piston pump to generate the injection pressure, in which the piston is retracted against a spring to withdraw fluid from a reservoir. At the end of the piston stroke (which may be adjustable) the piston is disengaged from the retracting mechanism and is urged suddenly by the spring to pressurise

and discharge the fluid from the delivery nozzle. The retracting mechanism may be manual or motorised. In some devices, the piston is driven on the discharge stroke by gas or an electric motor instead of a spring.

Manually operated injectors generate a pressure in the medicament of about 100 bars. In operation, the discharge orifice is placed a small distance (about 10mm) from the epidermis, and the high velocity jet strikes then penetrates the epidermis (free jet mode). The principle appears to be that the jet sacrifices some of its kinetic energy to puncture the epidermis, because if the nozzle is pressed firmly on the skin (contact mode), and the injector operated, the liquid is pressurised but has no kinetic energy, and is unable to pierce the skin. In the jet free mode, medicament is wasted, since some of the liquid is deflected sideways before puncture is completed, whilst in the contact mode, the epidermis deforms under the pressure of the liquid, which allows all of the medicament to escape without achieving penetration.

Powered injectors generate higher pressure - typically 600 bars or more, which is sufficient to penetrate the epidermis even when the discharge orifice is placed firmly on the skin (the contact mode). However, even in the contact mode a variable quantity of liquid is lost on each injection because the epidermis initially deforms before puncturing, and allows some liquid to escape. A further reason that the contact mode injectors leak is that often the orifice fitted to the injector is an artificial jewel of the type used for bearings in chronometers (because they are inexpensive, accurate, and efficient), but the method of mounting the jewel is such that the face of the orifice is always a small distance from the skin, and the consequent broadening of the jet results in lower force per unit area, and poor penetration.

The basic aim of all these devices is to apply the medicament with sufficient force to pierce the epidermis, but it is the rate of increase in force which is important

rather than the nominal pressure used, and few prior art injectors can achieve a sufficiently high rate of pressure rise to ensure reliable and repeatable injections.

Laboratory tests on both manual and powered injectors often give encouraging results, but in practical situations, such as the vaccination of animals, very variable amounts are injected - frequently over 50% of the vaccine may be wasted, because of hairs and dirt on the skin, and movement of the animal. The difficulty in achieving successful injections is exacerbated if the subject does not co-operate, as in the case of animals, young children or elderly patients. Premature operation of the injector is common, as is relative movement between the injector orifice and epidermis which can cause tearing of the epidermis during injection. The amount of contact pressure applied varies between operators, and the action of releasing the trigger mechanism frequently results in a jerk of the injector just as it operates, again causing poor injections and poor reproducibility.

Various methods have been proposed to overcome these problems, although in the case of the free jet types, little can be achieved. Powered injectors sometimes employ a vacuum device to suck the epidermis firmly onto the discharge orifice (see WO 82/02835 - Cohen, and EP-A-347190 - Finger) and thereby improve the seal between the orifice and the epidermis, and prevent relative movement. Alternatively, a pressure sensitive sleeve on the injector (see US-A-3859996 - Mizzy) is placed on the subject, whereby operation of the injector is prevented until the correct contact pressure between the orifice and skin is achieved.

Powered injectors have available a variety of sensing and control devices to enhance their performance, which are denied to manually powered injectors. However, they are frequently more complex and not easily adapted for portable use. The fact that they develop higher pressures than manual injectors means that their power consumption is

high; gas powered injectors require a heavy cylinder of compressed gas, and electrically powered injectors are often mains powered; battery powered injectors require a heavy battery pack, and the limited availability or inconvenience of the power sources has meant that the use of powered injectors has been mainly confined to mass vaccination programs. In the case of batteries and gas cylinders, it is usually difficult to judge the number of operations available from power stored. Furthermore, the sensing methods used to enable optimum operation are invariably secondary or indirect. For example, US-A-3859996 - (Mizzy) discloses a controlled leak method to ensure the injector orifice is correctly placed at the required pressure on the subject's skin. When the placement conditions are met, the controlled leak is sealed off by contact with the subject's skin, and the pressure within the injector control circuitry rises until a pressure sensitive pilot valve opens high pressure gas to the drive piston. However, the actual pressure of the orifice on the skin is not being measured; a hair, dirt or other irregularity on the skin or sealing face of the orifice will prevent or retard the pressure rise in the control circuit, and the operator will unconsciously press the injector harder onto the skin. Also the timing characteristics may vary because of the said ineffective sealing, hysteresis of the pressure switch, and variations in the supply pressure. In other words, the parameters being measured are the effectiveness of the seal of the controlled leak sensor on the skin and the pilot valve response, not the actual pressure of the orifice on the epidermis. Still other devices use a sliding sleeve in contact with the subject's skin, whereby displacement of the sleeve is used to initiate the injection, but this method measures the load on the sleeve, not on the orifice as required.

It may be seen therefore that whilst needle-less injection potentially is more efficient than hypodermic

needle injections for certain applications, the technique is very dependent on the ability of the operator and the compliance of the subject. Those injectors that have features designed to reduce these problems tend to be more complex and costly, and less portable. Furthermore, the simpler injectors designed for use by the patient are invariably complicated to load, clean, adjust and operate, and have not been particularly well designed to be "user friendly". For example, self injection of insulin by the diabetic patient has been an area of intense development, because such patients often have to inject themselves four time daily, and needle-less injectors offer the possibility of less pain and tissue damage. Nevertheless, the aforesaid variability in performance has prevented the widespread adoption of the technique, and the recommended cleaning and sterilization procedures are extremely inconvenient.

WO 93/03779 describes a needle-less injector of the present inventor, which aims to overcome, or at least mitigate, the problems described above. In summary, it provides a needle-less injector which comprises a chamber for containing liquid to be injected, the chamber being provided with a liquid outlet; a dispensing member movable in a first direction to reduce the volume of the chamber to cause liquid contained therein to be expelled through the said liquid outlet; and an impacting member arranged to strike the said dispensing member to cause movement thereof in the said first direction; the injector comprising a front portion which carries means defining said liquid outlet, a rear portion having means defining a handle for the injector, means for urging the rear portion away from the front portion, and means for actuating the injector, or permitting actuation thereof, in response to the movement of the rear portion towards the front portion against the force of the means urging them away from one another.

The injector described in WO 93/03779 has been found to give excellent results. The design described in detail

therein is, however, essentially one intended for dispensing a large number of doses, say 1500, and uses a built-in electric motor and battery to provide power. The present invention is directed at providing a needle-less injector which is suitable for dispensing a single dose, and which is sufficiently inexpensive that it can be disposed of thereafter.

The actuator of the present invention is adapted, in conjunction with a cartridge, to form a needle-less injector, the cartridge being pre-filled with a liquid to be injected in a subject, and having a liquid outlet and a free piston in contact with the liquid. The actuator comprises an impact member urged by a spring and temporarily restrained by a latch means, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet. The spring provides a built-in energy store and is movable from a higher energy state to a lower energy state, but preferably not vice versa. The actuator may comprise trigger means to operate the said latch, and thus initiate the injection, only when a predetermined contact force is achieved between the liquid outlet of the said cartridge and the subject.

In one aspect thereof, the invention provides an actuator as recited above, having a pressure pad which surrounds the said liquid outlet and is adapted in use to bear on the subject's skin. The pad is preferably designed to prevent ready removal of the cartridge.

In another aspect thereof, the invention provides an actuator as recited above, having a safety catch which has a first position, in which it prevents the latch permitting the impact member to move, and a second position, in which it does not prevent the latch permitting such movement.

In a further aspect, the actuator has a user-holdable portion and means for mounting the cartridge so that the user-holdable portion is movable relative to the cartridge

when the liquid outlet of the cartridge, and/or a pad surrounding the liquid outlet, is urged into contact with the subject against a force provided by at least one spring element integral with one of the said portions, and the said latch means comprises a latch member which is movable, by the said relative movement between the user-holdable portion and the cartridge, from a position in which it restrains movement of the impact member to a position in which it permits movement of the impact member.

The liquid outlet may be closed prior to use by a frangible sealing member. Preferably this sealing member is attached to a retaining member, for example a nut which retains the cartridge in the actuator.

It will be understood that the present invention includes not only needle-less injectors which do not have a separately identifiable cartridge, but also those which do not, for example where the liquid is held in a chamber which is an integral part of the device, and the term "cartridge" is to be construed as including such possibilities. Further the invention comprehends both injectors which are capable of being rearmed and reused and those which are not. It further comprehends other aspects which will be apparent from the description given herein.

The term "liquid" as used herein includes, *inter alia*, solutions, suspensions, emulsions and colloids.

The cartridge is preferably a hollow cylindrical cartridge containing the medicament, having an outlet orifice which may be formed as part of the cartridge, or comprising a separate nozzle sealingly fitted to the outlet end of the cartridge. Preferably the cartridge is made of glass. The glass, or any alternative material of which the cartridge may be made, is preferably transparent, and may have markings to indicate the amount of medicament contained therein. The outlet orifice is that which is placed directly on the epidermis to cause the injection. The cartridge may be supplied pre-filled for insertion in the apparatus by the user, or supplied ready fixed onto the

injector by the manufacturer.

The piston of the injector preferably comprises a material which is substantially non-resilient when subjected to a slowly applied force but is highly resilient when subjected to a rapidly applied force. The preferred material for the piston is polytetrafluoroethylene.

The cartridge may be a pre-filled cartridge as described heretofore, having an outlet end sealed by a frangible membrane. The cartridge can then be inserted into the apparatus and retained by a screw cap or similar device, interposed by a discharge nozzle with a piercing tube that punctures the frangible membrane so as to create an hydraulic connection with the medicament contained in the cartridge. Alternatively, the retaining cap may serve also as the nozzle, and have an integral piercing tube.

The medicament may be a one-part or multi-part liquid or liquid and solid which may be mixed immediately prior to injection.

Injectors in which the power source is reloadable, for example the prior art devices which have a reloadable spring, must employ a certain factor of safety to ensure a reasonable working life. This is because as the spring is repeatedly stressed and unstressed it gradually loses its resilience. This loss is most pronounced if the spring is fully stressed at the start of each working cycle. It is therefore necessary to operate with the spring stressed to less than the maximum possible extent, say 60% of the maximum. By contrast, when using a spring which is non-reloadable during use of the device, as in the present invention, one can employ a spring which is loaded to the maximum possible extent. One can therefore have a spring which is smaller for a given amount of stored energy, or more powerful for a given size of a spring. Either way, one achieves a significant increase in the energy density of the device, i.e. the amount of energy stored per unit volume. Also by avoiding any need for a mechanism for reloading the spring, the size, weight and complexity of

the device are reduced, and the problem of designing a reloading mechanism which is ergonomically correct is avoided.

In the described embodiment, operation of the latch is provided by a sliding sleeve assembled co-axially on the tubular body, and urgeable in a rearwards direction by a spring. This is preferably in the form of a cantilever spring formed as part of the sliding sleeve and bearing on a surface of the tubular body. Alternatively, the spring may be formed on the tubular body and the surface mentioned may be formed on the sleeve. In use, the injector orifice and/or a pressure pad surrounding the orifice, is placed on the subject's skin, and the injector is pushed firmly in the forward direction onto the skin by acting on the sliding sleeve. The sleeve moves forward against the force of the spring, and at a position representing the required contact force, a cam surface on the sleeve disengages the latch from the threaded rod, which accelerates under the action of the main spring to cause the injection, as described.

The injector may be configured so that it allows a selected medicament cartridge to be installed by the user, and retained within the tubular body by a screwed or bayonet fitting cap. A variation of this is for the medicament cartridge to be fitted with a frangible membrane seal instead of a discharge orifice, and for the orifice to be contained within the retaining cap, which has a piercing tube to puncture the membrane and make hydraulic connection with the medicament.

To enable the injection of two-part-drugs - for example a lyophilized (freeze dried) drug and a solvent - a further embodiment describes a method of storing and subsequently mixing the components prior to making an injection.

Figures 1 to 3 show, in longitudinal section, successive operating positions of an embodiment of the invention;

Figure 4 is a detailed view, on a larger scale showing the upper portion of the embodiment of Figures 1 to 3 in the position of Figure 2;

Figure 4a is a plan view showing the cooperation of a latch and ram in the embodiment of Figures 1 to 4; and

Figure 5 shows a modified version of the embodiment of Figures 1 to 4a; and

Figure 6 is a view similar to Figure 4, but showing a further embodiment.

Figure 1 shows another embodiment of injector 100, as supplied, loaded with injectate 101 which is contained in a cylindrical cartridge 102 which has a discharge orifice 103. A free piston 104 is sealingly located in cartridge 102 in contact with the injectate 101.

Cartridge 102 is retained onto a spring housing 105 by nut 106, which may have a flange 107 with means of tightening with a spanner. The outer end of nut 106 terminates in a frangible tab 108, to which is assembled a resilient seal 109. It is preferred that the cartridge is filled with injectate and assembled to the nut 106, which is an interference fit on the cartridge so that the nut is frictionally retained on the cartridge to ensure the resilient seal is biased onto the orifice 103 to seal against leakage and contamination. The interference fit further applies a beneficial compressive stress to the glass cartridge 102 (see our copending International Patent Application No. PCT/GB95/02649).

A pressure pad 110 is non-releasably attached to the nut 106, and serves to evenly distribute the contact pressure of the injector when it is placed on the skin to operate. Pressure pad 110 is free to rotate on the nut 106, so that the nut 106, and hence the cartridge 102, cannot be removed without recourse to a tool. The tool may be quite simple, and merely lock the nut 106 and pad 110 together, so that the nut 106 may be unscrewed by grasping the rim of the pad 110. Spanner access to the flange 107 on the nut 106 is prevented by arranging for a case 111 to

cover the flange 107. If desired, the pressure pad 110 can be supplied to the user as a separate item, and attached by the user (or not) as the user may decide.

The spring housing 105 is slidably located within case 111, and biased in direction K by one or more cantilever springs 112 acting on a cam surface 113 on housing 105. Alternatively, the heel of a latch 114 may cooperate with a cam surface 115 to achieve the same bias effect. The housing 105 is retained in case 111 by one or more retaining lugs 116 cooperating with the edges of apertures 117.

The spring housing 105 contains a metal ram 118, which is urged in the direction of arrow K by a spring 119, and temporarily restrained from movement by the latch 114. This is shown enlarged in Figures 4 and 4a. As can be seen there, the latch 114 has a "keyhole" aperture 126 which provides two points P which support the ram 118 on a face of a groove 120 in the ram. Thus the biasing force of the spring 119 on ram 118 is resisted on the larger flat area of the latch 114, which itself rests on the end of the spring housing 105. The preferred material for making the housing 105 is thermoplastic, and by ensuring that the loads resulting from storing the ram 118 in the biased condition are compressive, there is no likelihood of catastrophic failure due to creep.

Referring to Figure 1, to operate the injector it would be necessary to place the orifice 103 on the patient's skin and apply a force towards the skin by pushing on case 111. This would cause the spring housing 105 to move into the case against the bias of cantilever springs 112, so that the heel of latch 114 contacts cam surface 115. However, this movement is prevented by a security clip 121 which blocks relative movement between the case 111 and the housing 105. This prevents accidental operation and first it is necessary to snap off the frangible seal 108 together with resilient seal 109, and then unlatch the security clip 121, as shown in Figure 2.

Figure 3 shows the injector pressed on the skin 122, with the latch 114 operated by cam surface 115 to disengage from the ram 118. The ram 118 is accelerated rapidly so that face 118a of the ram 118 strikes the piston 104 and drives it forward to discharge the injectate 101 through the skin 122 into the underlying tissues. The impact of the ram 118 on the piston 104 causes a high skin-piercing pressure in the injectate 101, followed by discharge of the remaining injectate 101 at a lower pressure.

The modified embodiment shown in Figure 5 uses the same reference numerals as Figures 1 to 4, except for certain additional items. Figure 5 shows part of an injector in which the ram 118 is extended by the addition of a threaded part 130. A nut 131 is screwed onto the threaded part 130 and projects through a hole 132 in the end of the case 111. By adjusting a distance F by rotating the nut 131, the amount of travel of the ram 118 is thereby limited, as will now be described.

Release of the latch 114 permits the ram 118 to move in direction of the arrow A to cause injection as previously described. However, after the ram 118 has travelled the set distance F, a face 135 of the nut 131 contacts a face 136 of the latch 114 and stops the ram 118 short of its potential full travel. Thus the amount of injectate dispensed is less, and the range of adjustment may be that the amount of injectate delivered is from 0 to 100% of the full stroke capacity.

The nut 131 may have graduations 133 which may be set against a pointer 134 attached to, or integral with, the spring housing 105.

Figure 6 shows a modification which enables the injector to be re-armed, and thus to be reused once a fresh cartridge has been inserted. The modification consists of forming an integral hinge 124 in the wall of the case 111, thereby to define a pivotal latch barrier 123.

By pushing in the direction of arrow X on face 118a of ram 118, a conical end portion 125 of the ram 118 enters

the larger diameter portion of the keyhole 126 in latch 114, and pushes the latch 114 sideways. (This is normally prevented in this position because the latch barrier 123 is adjacent a face 127 of the latch 114). When groove 120 reaches the keyhole 126 in latch 114, the latch snaps into the groove, and the loading force on the ram 118 is removed. The injector is now re-armed, and latch barrier 123 is closed to act on the face 127 of the latch 114 and prevent the latch from accidental disengagement. Both the security clip 121 and the latch barrier 123 have latches or detents (not shown) that ensure firm engagement with the case 111 when closed.

A fresh cartridge can then be inserted. The cartridge may be supplied with a pressure pad 110 and nut 106 already attached, in which case all that has to be done is to screw the assembly of cartridge, pad and nut into the end of the actuator. Alternatively, only the cartridge may be supplied, in which case the original pad and nut are used. In either event, the same tool can be used as that described above for use in initial assembly of the injector. Of course, re-use of the device must be limited so as not to exceed the life of the components.

Whilst the shape of the nozzle may be such to achieve optimum sealing efficiency and comfort, the geometry of the orifice within the nozzle should have a length to diameter ratio of preferably not more than 2:1, preferably in the order of 1:2, and the exit of the orifice should be placed directly onto the epidermis. It is sometimes necessary to use multiple orifice nozzles, particularly when dispensing large volumes, and each orifice in the nozzle should ideally have a maximum L:D ratio of 2:1, preferably 1:2.

As mentioned earlier, the cartridges used in the present invention are preferably made of glass. In a preferred embodiment thereof, the forward end of each cartridge has a circular hole of preferably from 0.15 to 0.5mm diameter formed therein as the outlet orifice. The free piston in the cartridge is of a suitably inert

material, and polytetrafluoroethylene (PTFE) is preferred as the material for the whole or part thereof. PTFE has the advantage that its coefficients of static and dynamic friction are similar to one another and extremely low (about 0.01). It also has the property that it is substantially non-resilient when subjected to a slowly applied force but is highly resilient when subjected to a rapidly applied force. This makes it particularly suitable for use in the context of the present invention, where a rapidly applied force is exerted on the piston at the time of impact. Other materials which can be used instead of PTFE, or in combination therewith, include tetrafluoroethylene-hexafluoropropylene copolymer, tetrafluoroethylene-ethylene copolymer, polychlorotrifluoroethylene, poly (vinylidene fluoride), tetrafluoroethylene-perfluoro(propyl vinyl ether) copolymer, and hexafluoroisobutylene-vinylidene fluoride copolymer. Yet another material which can be used is acetal, though this is believed not to have the resilient/non-resilient property which characterises PTFE. The initial diameter of the free piston, at least when made of PTFE, can be greater than the internal diameter of the cartridge by up to about 0.25mm. When forced into the cartridge, the creep of the PTFE is sufficient to allow this, and the resulting seal between the piston and wall of the cartridge is excellent. This makes it possible to use wide tolerance, low cost, glass tubing for the manufacture of the cartridge.

CLAIMS:

1. An actuator adapted, in conjunction with a cartridge, to form a needle-less injector, the cartridge being filled with a liquid to be injected in a subject, and having a liquid outlet and a free piston in contact with the liquid, the actuator comprising:
an impact member urged by a spring and temporarily restrained by a latch, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet, the spring providing a built-in energy store and being movable from a higher energy state to a lower energy state, the actuator further comprising a pressure pad which surrounds the said liquid outlet and is adapted, in use, to bear on the subject's skin.
2. An actuator as claimed in claim 1, wherein the said spring is a mechanical spring.
3. An actuator according to claim 1, wherein the spring is a compressed air spring.
4. An actuator according to any preceding claim, which is provided with means for retaining the cartridge in such a way as to prevent removal of the cartridge except by use of a tool.
5. An actuator according to claim 1, wherein the liquid outlet is closed by a frangible membrane.
6. An actuator according to any preceding claim, further comprising a safety catch which has a first position in which it prevents the latch permitting the impact member to move, and a second position, in which it does not prevent the latch permitting such movement.

7. An actuator according to any preceding claim, having a user-holdable portion and means for mounting the cartridge so that the user-holdable portion is movable relative to the cartridge when the pressure pad is urged into contact with the subject against a force provided by at least one spring element integral with one of the said portions, and the said latch means comprises a latch member which is movable, by the said relative movement between the user-holdable portion and the cartridge, from a position in which it restrains movement of the impact member to a position in which it permits movement of the impact member.
8. An actuator according to claim 7, wherein said integral spring element is a cantilever spring integral with one of said portions and acting on a cam surface of the other of said portions.
9. An actuator adapted, in conjunction with a cartridge, to form a needle-less injector, the cartridge being filled with a liquid to be injected in a subject, and having a liquid outlet and a free piston in contact with the liquid, the actuator comprising:
an impact member urged by a spring and temporarily restrained by a latch, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet, the spring providing a built-in energy store and being movable from a higher energy state to a lower energy state, the actuator having a user-holdable portion and means for mounting the cartridge so that the user-holdable portion is movable relative to the cartridge when the pressure pad is urged into contact with the subject against a force provided by at least one spring element integral with one of the said portions, and the said latch means comprises a latch member which is movable, by the said relative movement between the user-holdable

portion and the cartridge, from a position in which it restrains movement of the impact member to a position in which it permits movement of the impact member.

10. An actuator according to claim 9, wherein said integral spring element is a cantilever spring integral with one of said portions and acting on a cam surface of the other of said portions.

11. An actuator adapted, in conjunction with a cartridge, to form a needle-less injector, the cartridge being filled with a liquid to be injected in a subject, and having a liquid outlet and a free piston in contact with the liquid, the actuator comprising:

an impact member urged by a spring and temporarily restrained by a latch, the impact member being movable in a first direction under the force of the spring to first strike the free piston and then to continue to move the piston in the first direction to expel a dose of liquid through the liquid outlet, the spring providing a built-in energy store and being movable from a higher energy state to a lower energy state, the actuator further comprising a safety catch which has a first portion, in which it prevents the latch permitting the impact member to move, and a second position, in which it does not prevent the latch permitting such movement.

12. An actuator according to claim 11, wherein said safety catch is integral with an exterior wall of the actuator.

13. An actuator according to any preceding claim, wherein the spring is not movable after use from the lower energy state to the higher energy state, whereby the actuator is non-rearmable.

14. An actuator according to any one of claims 1 to 12, wherein the spring is movable after use from the lower

energy state to the higher energy state, whereby the actuator is rearmable.

15. A needle-less injector comprising an actuator according to any preceding claim and a cartridge.

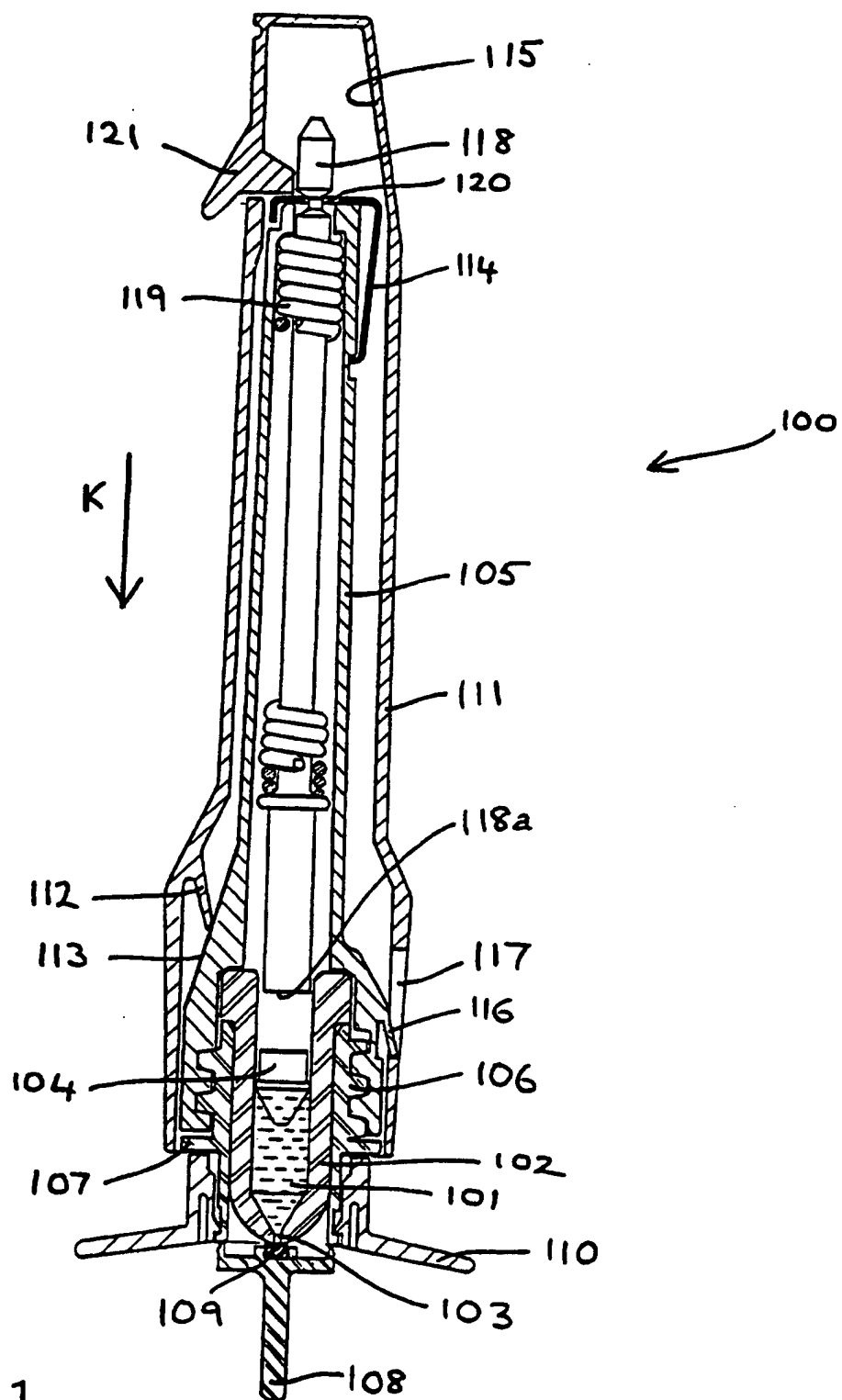


FIG 1

2/6

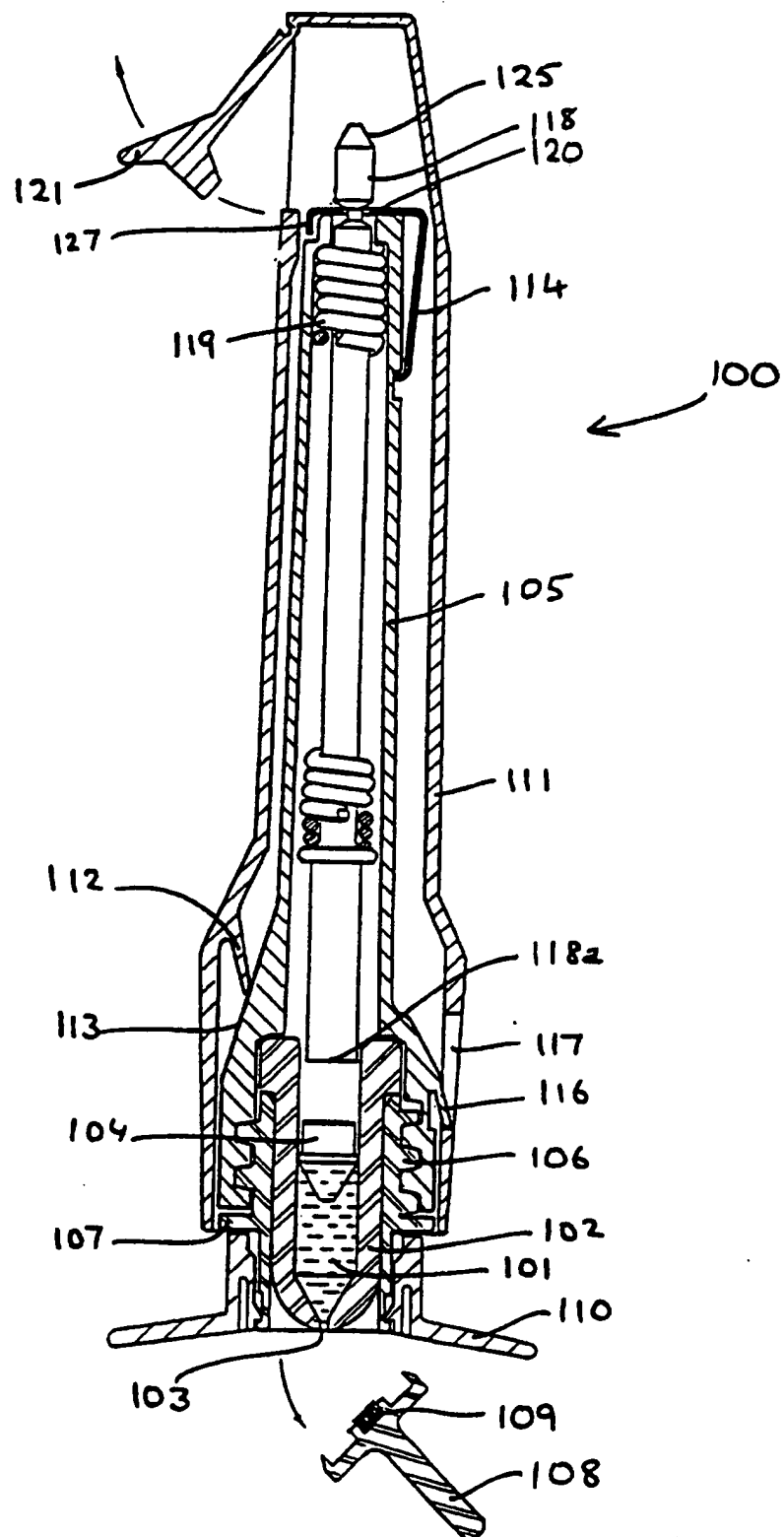


FIG 2

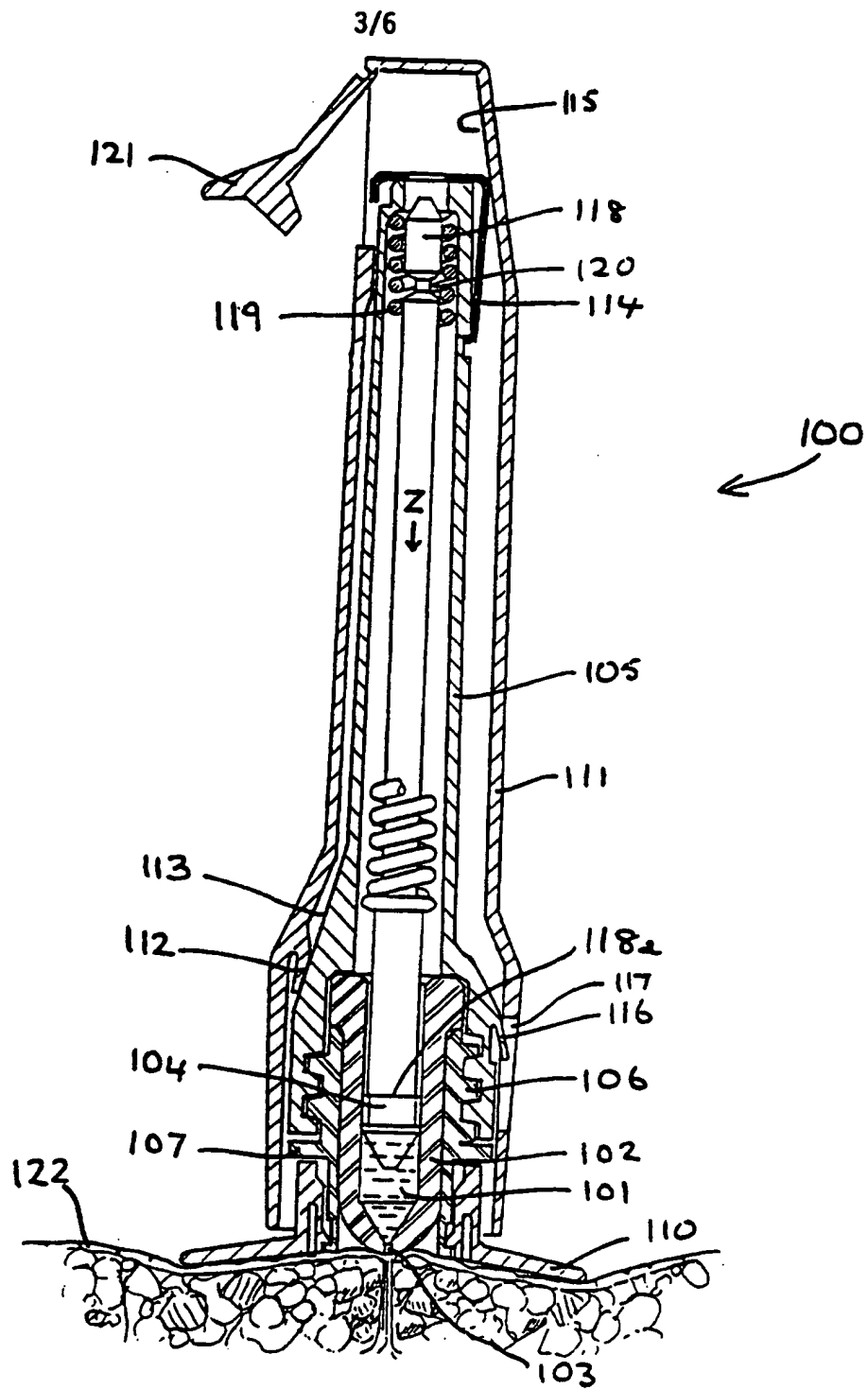
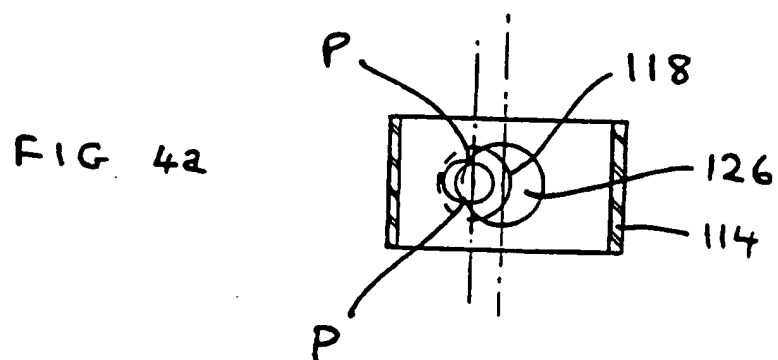
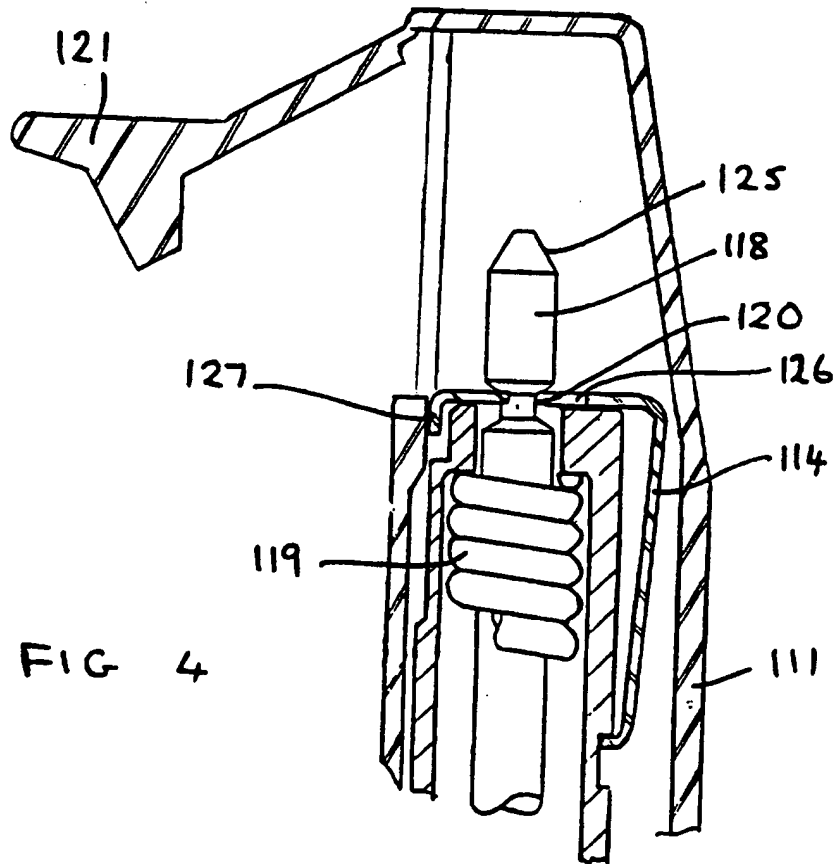
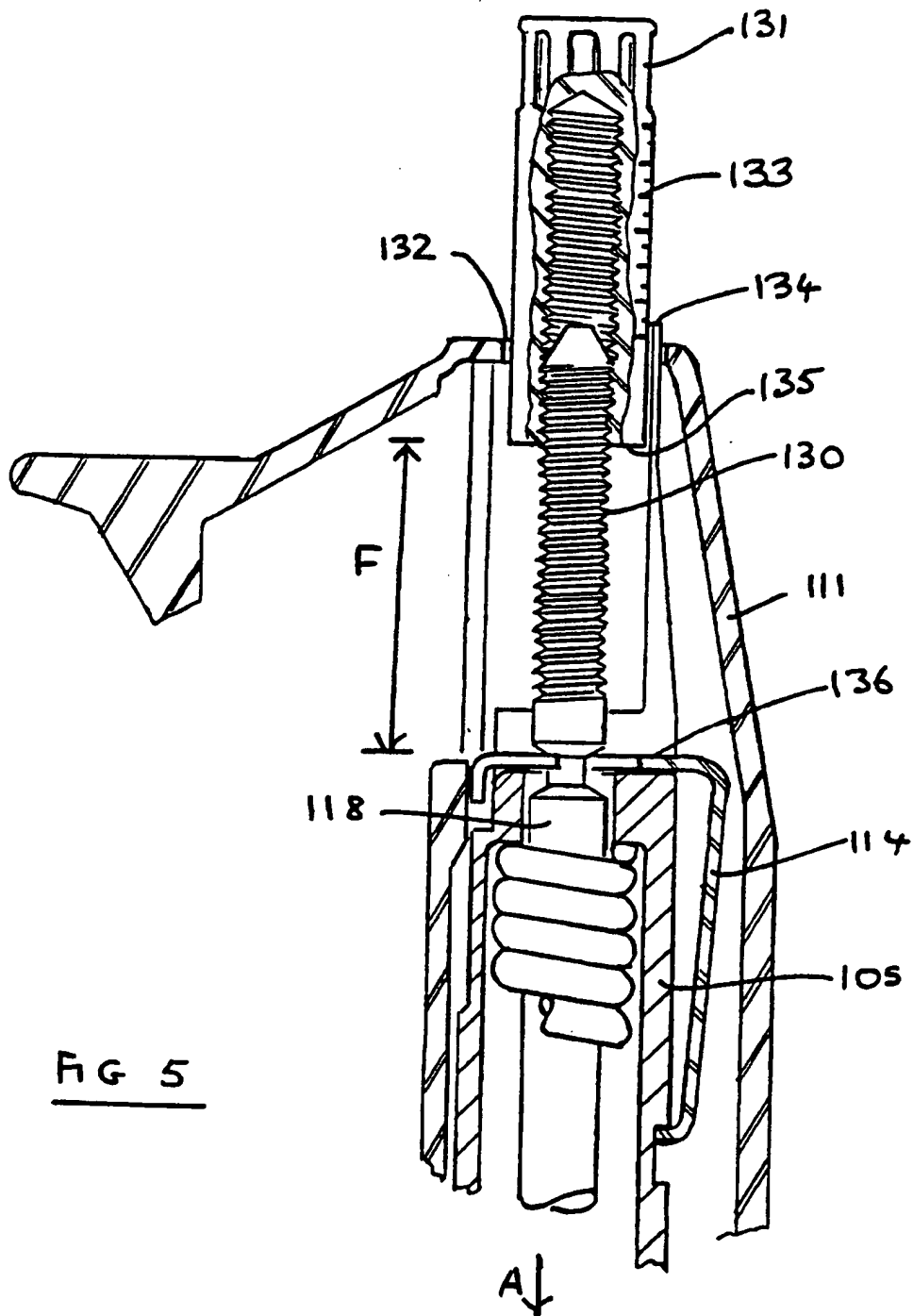


FIG 3





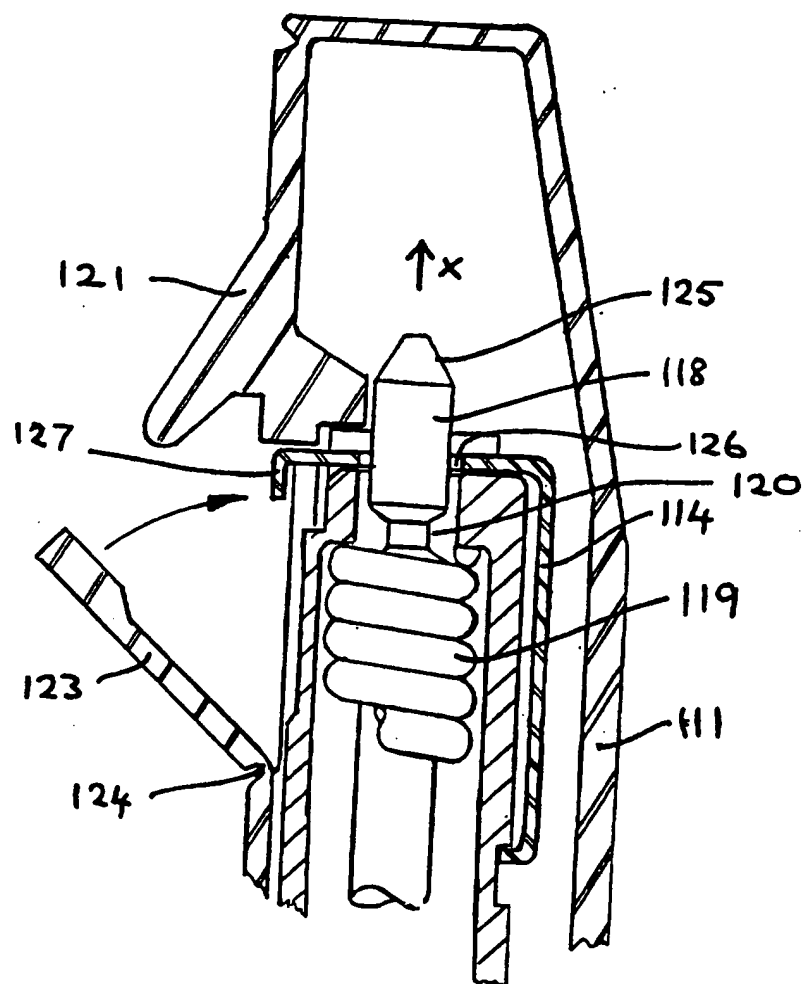


FIG 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 96/00190

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|-----------------------------|
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| X | US,A,2 398 544 (LOCKHART) 16 April 1946 see page 1, column 2, line 3 - page 2, column 1, line 75 see figures 2-4 --- | 1,2,4 |
| A | | 7,9 |
| X | CH,A,294 905 (SCHERER CORPORATION) 16 February 1954 see page 3, line 80 - page 7, line 20 see page 9, line 76 - line 89 see figures 4,5,10A --- -/- | 1,2,7,9, 15 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- * "&" document member of the same patent family

Date of the actual completion of the international search

26 April 1996

Date of mailing of the international search report

09.05.96

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Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

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PCT/GB 96/00190

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | US,A,4 596 556 (MORROW ET AL.) 24 June 1986 see column 5, line 54 - column 6, line 10 see figures 3-6 --- | 3,7,9 |
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International Application No

PCT/GB 96/00190

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